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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,317	05/25/2000	Boris Shkolnik	CRD0852	5734

7590 05/19/2004

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EXAMINER	
DESANTO, MATTHEW F	

ART UNIT	PAPER NUMBER
3763	21

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/578,317	SHKOLNIK, BORIS	
	Examiner	Art Unit	
	Matthew F DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimada et al. (USPN 4,819,751) and further in view of Rydell (USPN 4811737), and Burns et al. (UPSN 5176698).

Shimada et al. disclosed a balloon catheter with an outer tube (13), and inner tube (21) with a guide wire lumen (43), a balloon (23), a vent (35), a coupling member (33) but fails to disclose the balloon being coupled to a syringe and the specific size of the apertures. (Figure 2)

Rydell discloses the specific size of venting ports in a balloon catheter, where the size of the hole is between 0.0005 to 0.0015 inches. (Column 3, lines 22-37 and Column 4, lines 10-24).

Burns et al. the material and the ability to use a gas permeable balloon to increase the air vented through the balloon and decrease the chance of releasing air in the blood vessel.

At the time of the invention it would have been obvious to one of ordinary skill in the art to combine Shimada et al. with Rydell and Burns et al. because it is well known in the medical art to use a syringe to inject fluid into a catheter to inflate a balloon (as

taught by Burns et al.), and the motivation for making the apertures 0.0005 to 0.0015 is because this size would have been able to permit air to be vented and preclude the outflow of liquid as well as prevent the inflow of air back in the catheter as taught by Rydell col. 4, lines 10-24.

2. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jang (USPN 4,744366) and further in view of Rydell (USPN 4811737), and Burns et al. (UPSN 5176698).

Jang disclosed a balloon catheter with an outer tube (12), and inner tube with a guide wire lumen (22), a balloon (42), a vent (36), and a coupling member but fails to disclose the balloon being coupled to a syringe and the specific size of the apertures. (Figure 21)

Rydell discloses the specific size of venting ports in a balloon catheter, where the size of the hole is between 0.0005 to 0.0015 inches. (Column 3, lines 22-37 and Column 4, lines 10-24).

Burns et al. the material and the ability to use a gas permeable balloon to increase the air vented through the balloon and decrease the chance of releasing air in the blood vessel.

At the time of the invention it would have been obvious to one of ordinary skill in the art to combine Jang with Rydell and Burns et al. because it is well known in the medical art to use a syringe to inject fluid into a catheter to inflate a balloon (as taught by Burns et al.), and the motivation for making the apertures 0.0005 to 0.0015 is

because this size would have been able to permit air to be vented and preclude the outflow of liquid as well as prevent the inflow of air back in the catheter as taught by Rydell col. 4, lines 10-24.

3. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jang and Burns et al. and Rydell as applied to claims 11-14 above, and further in view of Carlblom (USPN 5637365) and Follmer et al. (5728065).

Jang and Burns et al. and Rydell disclosed the claimed invention having a balloon being made of a polymer and the polymer being polyolefin, but never described the characteristics of the balloon, such as the balloon being gas permeable, Jang and Burns et al. and Rydell failed to disclose placing the balloon in a protective tube.

Carlblom discloses that polyolefin is a "gas-permeable material." Column 10, lines 18-49.

Follmer et al. discloses the use of a constraining member (ref #. 200), to be placed over the inflatable balloon

At the time of the invention, it would have been obvious to a person of ordinary to make the inflatable balloon out of a gas permeable material by Carlblom and to place the balloon in a constraining member taught by Follmer et al. with the invention of Jang and Burns et al. and Rydell.

The suggestion/motivation for making the balloon out of a gas permeable material is taught by Jang and Burns et al. and further supported by Carlblom col. 10, lines 18-40, where Carlblom teaches that polyolefin is a polymer that is gas permeable, and the motivation for the protective tube or constraining member was to limit the radial

expansion of the balloon but at the same time expanding the balloon allowing for a greater rate of gas and liquid to be flushed out of the vent hole, under normal inflation pressure (Follmer et al. column 7, line 45-column 8, line 14).

4. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimada et al. and Burns et al. and Rydell as applied to claims 11-14 above, and further in view of Carlblom (USPN 5637365) and Follmer et al. (5728065).

Shimada et al. and Burns et al. and Rydell disclosed the claimed invention having a balloon being made of a polymer and the polymer being polyolefin, but never described the characteristics of the balloon, such as the balloon being gas permeable, Shimada et al. and Burns et al. and Rydell failed to disclose placing the balloon in a protective tube.

Carlblom discloses that polyolefin is a "gas-permeable material." Column 10, lines 18-49.

Follmer et al. discloses the use of a constraining member (ref #. 200), to be placed over the inflatable balloon

At the time of the invention, it would have been obvious to a person of ordinary to make the inflatable balloon out of a gas permeable material by Carlblom and to place the balloon in a constraining member taught by Follmer et al. with the invention of Shimada et al. and Burns et al. and Rydell.

The suggestion/motivation for making the balloon out of a gas permeable material is taught by Shimada et al. and Burns et al. and further supported by Carlblom

col. 10, lines 18-40, where Carlblom teaches that polyolefin is a polymer that is gas permeable, and the motivation for the protective tube or constraining member was to limit the radial expansion of the balloon but at the same time expanding the balloon allowing for a greater rate of gas and liquid to be flushed out of the vent hole, under normal inflation pressure (Follmer et al. column 7, line 45-column 8, line 14).

Response to Arguments

5. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
Art Unit 3763
May 17, 2004

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700